

REMARKS

Claims 1, 66, 68-72, 78, 126-132, 167-170, and 172 are pending in this application.

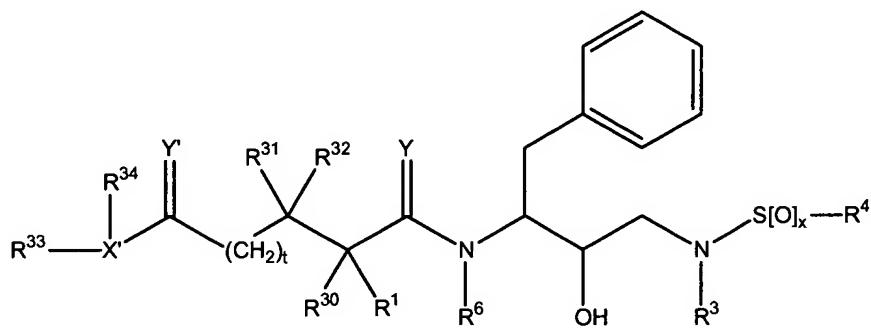
Claims 68-72, 127-131, 168-170, and 172 have been withdrawn as being directed to non-elected subject matter, in view of the Restriction Requirement imposed in a phone conversation with Applicants' undersigned representative on February 10, 2005.

Restriction Requirement under 35 U.S.C. §121 and Election of Species

i) Election

The Office Action has imposed a restriction requirement between the compounds of Group I (claims 1, 66, 78, 126, 132, and 167), and the methods of their use of Group II (claims 68-72, 127-131, 168-170, and 172). This restriction requirement acknowledges that the subject matter of Groups I and II constitute separately patentable inventions. MPEP § 806.04(h).

In response, Applicants affirm the provisional election of the invention of Group I, as indicated in the February 10, 2005 phone conversation between the Examiner and Applicants' undersigned representative. Claim 1 of Group I recites a compound represented by the formula:

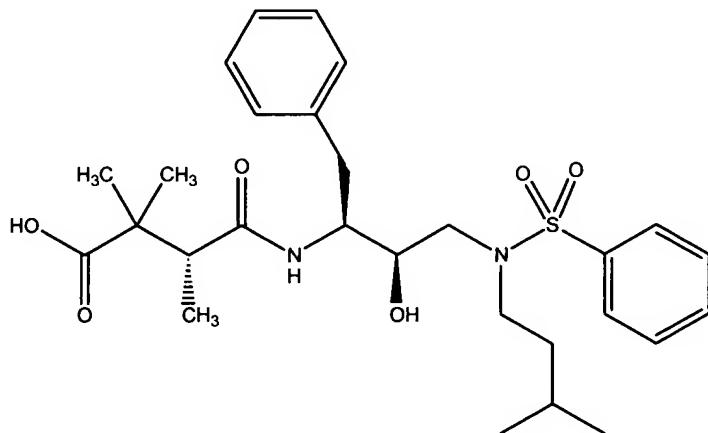


or a pharmaceutically acceptable salt thereof, wherein x, t, R¹, R³, X', Y, Y', R⁴, R⁶, R³⁰, R³¹, R³², R³³, and R³⁴ are as defined in claim 1.

Applicants also hereby affirm the provisional election for examination the species which is the compound:

[1S-[1R*(S*),2S*]]-4-[[2-hydroxy-3-[(3-methylbutyl)(phenylsulfonyl)amino]-1-(phenylmethyl)propyl]amino]-2,2,3-trimethyl-4-oxo-butanoic acid.

This compound has the structure



and is a compound of claim 1, wherein x is 2, t is 0, R¹ is methyl (an alkyl radical, as claimed), R³ is i-amyl (an alkyl radical, as claimed), X' is O, Y is O, Y' is O, R⁴ is phenyl (an aryl radical, as claimed), R⁶ is hydrogen, R³⁰ is hydrogen, R³¹ is methyl (an alkyl radical, as claimed), R³² is methyl (an alkyl radical, as claimed), R³³ is hydrogen; and since X' is O, R³⁴ is absent (as claimed).

The elected species is described in Example 6, Part B, at page 36, line 26 to page 37, line 9 of the specification, with respect to its synthesis. The elected species is described with respect to its molecular weight determination in Table 1, Entry 2, at page 39 of the specification. The elected species is described with respect to its measured retroviral protease inhibitory activity (IC₅₀) and biological efficacy (EC₅₀) in Table 9, Entry 1, at page 65 of the specification.

Claims 1, 66, 132, and 167 read on this elected species.

ii) Compounds Embracing the Elected Species and within the Same Inventive Concept

Pages 4-6 of the Office Action state

...upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice).

* * *

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice (emphasis in original).

In response, Applicants respectfully submit that the entire scope compounds embraced by claim 1, is within the same “inventive concept.” This is evidenced by the issuance of related U.S. Patent Nos. 6,727,282; 6,469,207; 6,313,345; 6,022,994; 5,760,076; 5,714,605 and 5,463,104, having claims of comparable or even broader scope than the now-pending elected claims of Group I. As such, claims 1, 66, 78, 126, 132, and 167 are directed to a single invention and should be examined without restriction among Markush group members.

In particular, now that Applicants have complied with the election-of-species requirement, they are entitled to full examination on the merits of elected claims 1, 66, 78, 126, 132, and 167 of Group I. According to MPEP § 803.02, in Markush claim practice,

...the examiner may require a provisional election of a single species prior to examination on the merits. ...Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. (emphasis added).

....
On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the

Markush-type claim with respect to a *non-elected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration.

Furthermore, MPEP § 803.02 states, “[I]t is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.” (emphasis added). Unity of invention is based on well-settled judicial precedent. For example, the MPEP cites *In re Harnisch* and *Ex parte Hozumi*. 206 U.S.P.Q. 300 (C.C.P.A. 1980) and 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984). In *Harnisch*, the Court of Customs and Patent Appeals rejected the imposition of a restriction requirement in a Markush-type claim where all of the compounds had a single use, and thus had unity of invention. Likewise, in *Hozumi*, the Board of Patent Appeals and Interferences (hereinafter “Board”) reversed a rejection of a Markush-type claim, where the compounds were core structures having plural diverse pendant moieties.

Other decisions reinforce the proposition that unity of invention is based on a common utility. For example, in *In re Jones*, the Court of Customs and Patent Appeals reversed the Board’s ‘improper Markush group’ rejection precisely because the claimed compounds had a common function. 162 F.2d 479, 74 U.S.P.Q. 149 (C.C.P.A.1947). In *Ex parte Dahlen*, 42 U.S.P.Q. 208 (Bd. App. 1938), the Board permitted claims to compounds having a common core with pendant widely-varying side chains, because the claimed compounds had common properties.

Based on the above decisions, claims 1, 66, 78, 126, 132, and 167 have unity of invention, because these claims embrace a single inventive concept. The compounds of these claims are retroviral protease inhibitors. These have a single common core and pendant moieties, as set forth in the definitions of x, t, R¹, R³, X', Y, Y', R⁴, R⁶, R³⁰, R³¹, R³², R³³, and

R³⁴. No matter which combination of pendant moieties is selected, the resulting compound is a retroviral protease inhibitor. Such compounds may also have other uses, but all are retroviral protease inhibitors. To restrict claims 1, 66, 78, 126, 132, and 167 to any scope less than their full scope is contrary to established precedent and M.P.E.P. guidance.

iii) Rejoinder of Process Claims 68-72, 127-131, 168-170, and 172 (M.P.E.P. § 821.04)

Page 8 of the Office Action states

Where Applicant[s] elect[] claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claims will be rejoined in accordance with the provisions of M.P.E.P. § 821.04.

Applicants have elected product claims. Moreover, the process claims 68-72, 127-131, 168-170, and 172, by virtue of their dependency on the elected product claims, are of the same scope and therefore comply with the requirements under M.P.E.P. § 821.04 for rejoinder. Upon a finding that the elected product claims are allowable, the process claims must be rejoined. See M.P.E.P. § 821.04.

Applicants therefore respectfully request (1) withdrawal of the restriction requirement and (2) rejoinder of withdrawn process claims 68-72, 127-131, 168-170, and 172, upon a finding that the elected product claims are allowable.

The Nonstatutory Double Patenting Rejection of Claims 1, 66, 78, 126, 132, and 167

Claims 1, 66, 78, 126, 132, and 167 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 14 of U.S. Patent No. 5,463,104.

In the interest of expediting prosecution, Applicants submit herewith a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) over the above-cited U.S. Patent No. 5,463,104, as well as related U.S. Patent Nos. 6,727,282; 6,469,207; 6,313,345; 6,022,994;

5,760,076; and 5,714,605.

Reconsideration and withdrawal of this rejection are respectfully requested.

“Potential” Double Patenting

The Office Action acknowledges that the pending claims are patentable over U.S. Patent No. 6,515,024 and pending U.S. Application Serial No. 10/315,024.

Applicants respectfully disagree with the Office Action’s suggestion that overlap is possible between those compounds embraced by the pending claims and those disclosed in U.S. Patent No. 6,515,024 or U.S. Application Serial No. 10/315,024. The group “ $-N(R^4)R^7R^7(CH_2)_nR^8$ ” (bonded directly to the core sulfur atom) of these disclosures cannot be “di-substituted aminoalkyl radical, substituted with heteroaryl,” as proposed in the Office Action’s hypothetical “overlapping” compound.

In fact, none of the compounds in the cited references overlap with the claimed compounds.

CONCLUSION

In summary, Applicants have now elected a species, in response the restriction requirement imposed in the Office Action. MPEP § 803.02 requires full examination of claims reading on the elected species. Restriction of claims 1-6, 8, 14, 15, 18, and 19 to any scope less than their full scope is improper.

In view of the Terminal Disclaimer under 37 C.F.R. § 1.321(c), filed herewith, all pending claims of this application are believed to be in condition for allowance. Acknowledgement of the same is respectfully requested, together with rejoinder of withdrawn process claims 68-72, 127-131, 168-170, and 172, as required under M.P.E.P. § 821.04.

This response is believed to completely address all of the substantive issues raised in the Office Action dated March 15, 2005.

Respectfully submitted,

By: 
Joseph M. Skerpon
Registration No. 29,864

Date: June 15, 2005

BANNER & WITCOFF, LTD.
1001 G Street, NW
Washington, DC 20001
202-824-3000